K093301

510(k) Summary

NOV - 6 2009

TurboHawk™ Peripheral Plaque Excision System

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.
Applicant	ev3 Inc.
Submitter	ev3 Inc. 3033 Campus Drive Plymouth, MN 55441 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	Brenda Johnson
Date Prepared	October 8, 2009
Device Trade Name	TurboHawk™ Peripheral Plaque Excision System
Device Common Name	Catheter, Peripheral, Atherectomy
Classification Name	Intraluminal Artery Stripper 21 CFR 870.4875, Product Code MCW
Classification Panel	Cardiovascular
Predicate Devices	SilverHawk™ Peripheral Plaque Excision System (K061188)
Intended use	Treatment of de novo and restenotic atherosclerotic calcified and non-calcified lesions located in native peripheral arteries.
Device Description	The TurboHawk Peripheral Plaque Excision System (TurboHawk Catheter and SilverHawk™ Cutter Driver) is designed for the treatment of de novo and restenotic calcified and non-calcified atherosclerotic lesions located in native peripheral arteries. The TurboHawk Catheter consists of a flexible shaft designed to track over a 0.014" guidewire. At the distal end of the TurboHawk Catheter is a small cutting assembly comprised of a rotating inner cutter contained within a tubular housing. The proximal end of the TurboHawk Catheter contains a connector and cutter positioning lever (thumb switch) designed to fit into the SilverHawk Cutter Driver. The SilverHawk Cutter Driver is a handheld, disposable, battery-driven unit (Catalog No: 02550) which powers the system. The TurboHawk Peripheral Plaque Excision System has two switches: 1) the SilverHawk Cutter Driver main power switch and 2) the TurboHawk Catheter thumb switch. The SilverHawk Cutter Driver

	main power switch supplies power to the device when turned ON. The TurboHawk Catheter thumb switch activates the drive shaft and engages the cutter when pulled proximally to the ON position. With the cutter engaged, the TurboHawk Catheter is slowly advanced across the lesion, shaving occlusive material from the artery. The excised tissue is captured and stored in the tip of the device. The cutting process is completed by advancing the TurboHawk Catheter thumb switch distally deactivating the drive shaft and disengaging the cutter. The TurboHawk Catheter thumb switch is fully advanced distally to the OFF position in order to pack the excised plaque into the tip. This cutting sequence is repeated as necessary to achieve the desired degree of plaque excision.
Performance data	Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.
Summary of Substantial Equivalence	The TurboHawk Peripheral Plaque Excision System has the following similarities to the predicate device: • Identical indications for use • Similar intended use • Similar materials • Similar fundamental scientific technology • Similar operating principle
Conclusion	Based on the identical indications for use, similar technological characteristics, materials and operating principle, and the results from safety and performance testing, the TurboHawk Peripheral Plaque Excision System is considered substantially equivalent to the SilverHawk Peripheral Plaque Excision System (K061188).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV - 6 2009

ev3, Inc.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K093301
Trade/Device Name: TurboHawk Peripheral Plaque Excision System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: October 20, 2009
Received: October 21, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K093301

Device Name: TurboHawk Peripheral Plaque Excision System

Indications for Use:

The TurboHawk Peripheral Plaque Excision System is intended for use in atherectomy of the peripheral vasculature. The TurboHawk Catheter is NOT intended for use in the coronary, carotid, iliac, or renal vasculature.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093301